

B669

CPE-215 Physical Attributes:

- Stable indefinitely as a raw material
- Stable in typical formulations studied for up to 48 months under accelerated conditions
- Available in high purity by GMP manufacture (food & cosmetic)
- Compatible with most formulation types



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CPE-215 – application examples

Compatible formats: gel, cream, ointment, patch, tablet, capsule, liquid, lacquer

- ⇒ Topical finger/toe nail penetration
- ⇒ Topical dermal – local effect
- ⇒ Topical dermal – systemic effect
- ⇒ Ophthalmic
- ⇒ Oral absorption enhancement
- ⇒ Nasal – systemic effect
- ⇒ Compatible with 'patch' constituents



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Advantages of CPE-215

- GRAS Excipient for food and cosmetic use
 - Approved by FDA as a Direct Food Additive (21 CFR 172.515)
 - Approved as a Fragrance
 - Approved as a Flavor Enhancer
- Excellent Transdermal Enhancement
 - Format Independent, i.e. effective in Patches, Gels, Ointments, Lotions, Creams
 - Compatible With Most Materials, Including Adhesives
- Non Irritating
- Stable excipient
- Available 99+% under food & cosmetic GMP



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Proposed Mechanisms of Action

- **Barrier Function Modification**
 - ⇧ Alteration of the cellular and intercellular lipid composition
 - By adding “lipid” (fluidization)
 - By subtracting lipids (dissolution/extraction of stratum corneum lipids)
 - ⇧ Affecting intercellular organization and cohesion
 - ⇧ Disruption or reordering of the water structure
 - ⇧ Alteration of stratum corneum proteins
- **Partitioning Effects**
 - ⇧ Both S.C. and Formulation Based
- **Thermodynamic Activity**
 - ⇧ Formulation Based



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CPE-215 Safety Studies:

Data available

- Not mutagenic (4 studies, 2001)
- No intranasal irritation - 3 times daily for 28 days in rat (VA Tech Aug 2000)
- Human studies - no local effects in nail lacquer studies
- GRAS status granted for food and cosmetic use (21 CFR 172.515, EAFUS database)
- Drug Master File (Type IV - #10260, 1993).

Data summaries only (1972-74)

- Acute oral LD₅₀ in rats > 5 g/kg
- Acute dermal LD₅₀ in rabbits > 5 g/kg
- Primary eye irritation - at 100% not an irritant
- Skin irritation - not an irritant when applied full strength to rabbits even under occlusion - intact or abraded skin



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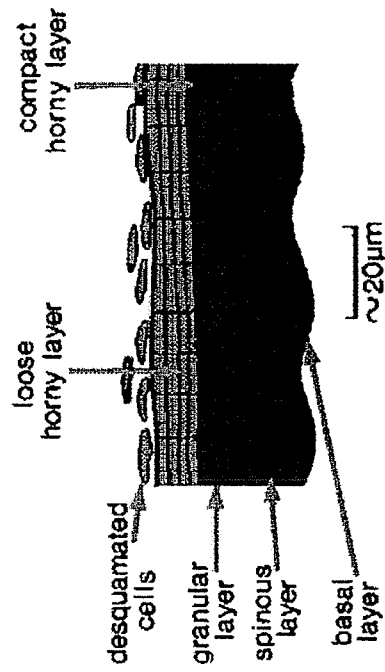
In vitro & In vivo studies
Franz Cell and Animal data

Diclofenac
Clotrimazole
Itraconazole
Ketoconazole
Testosterone
Estradiol

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Skin Structure

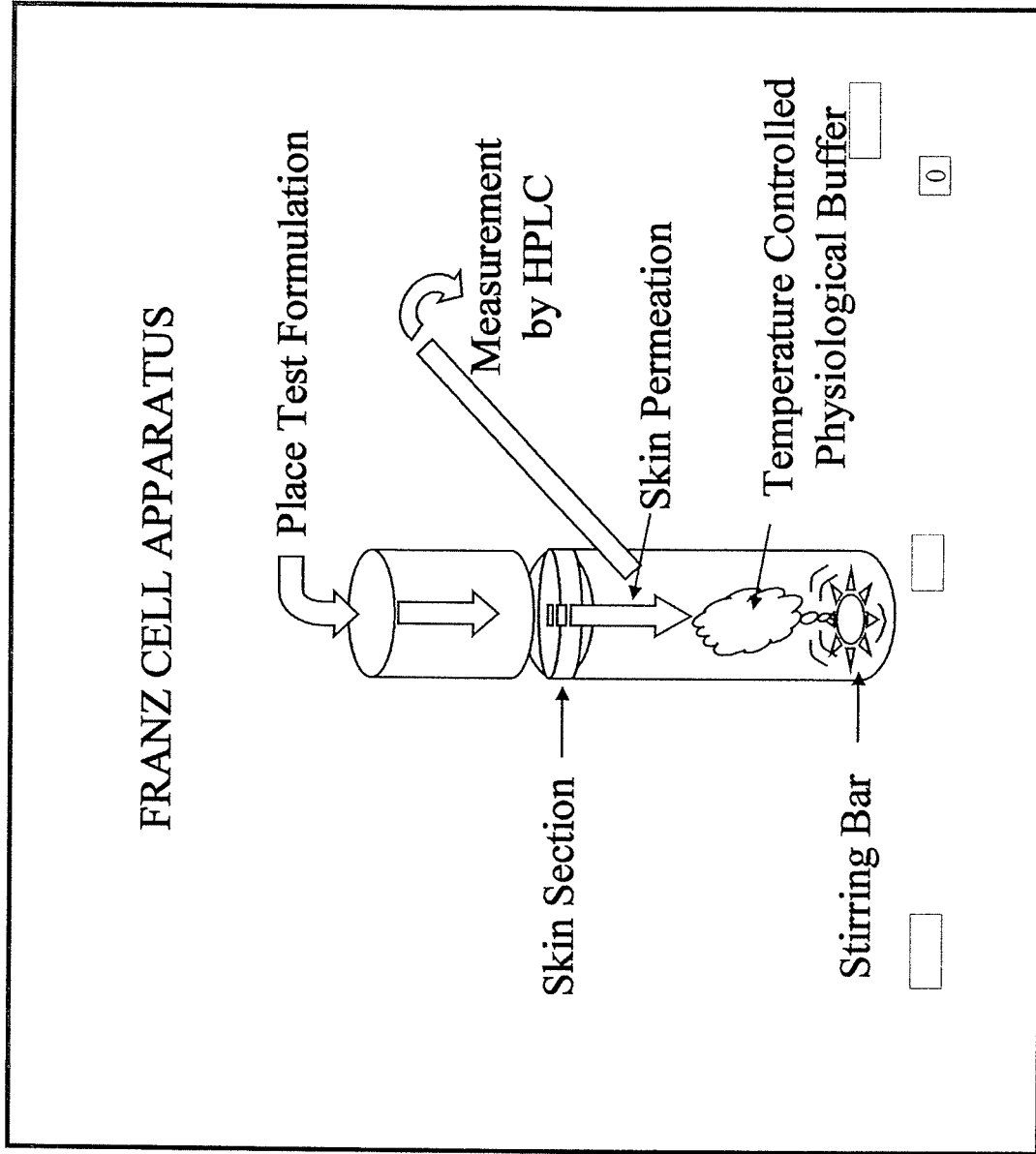


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Franz Cell Transdermal Testing



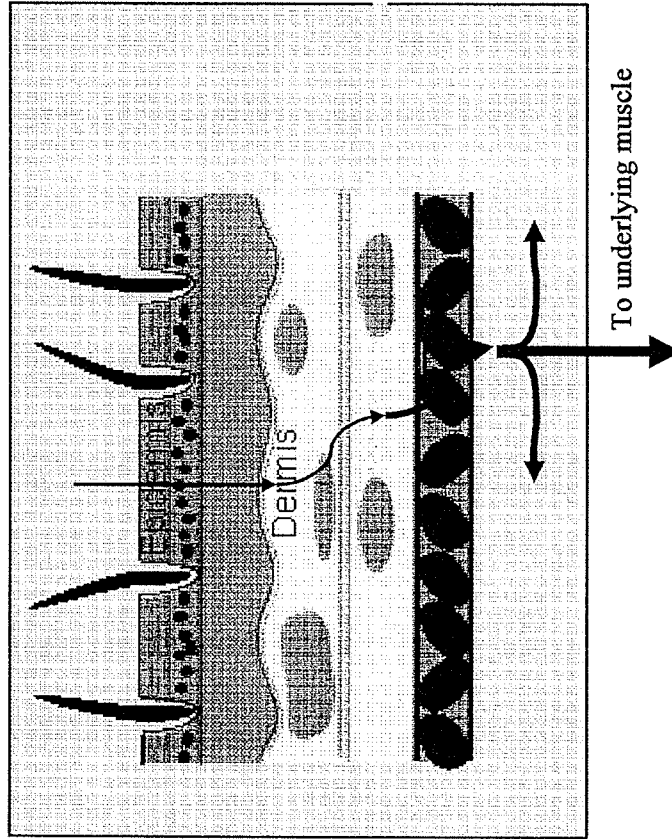
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Pharmaceuticals, Inc.

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Insufficient Flux Problem



Problem: For regional or systemic delivery, if flux is too small, drug molecules get “picked off” as they travel a tortuous path. They are removed by diffusion, metabolism, and the lymphatic / circulatory system. If they traverse too slowly, only sub therapeutic concentrations are presented to the desired region.



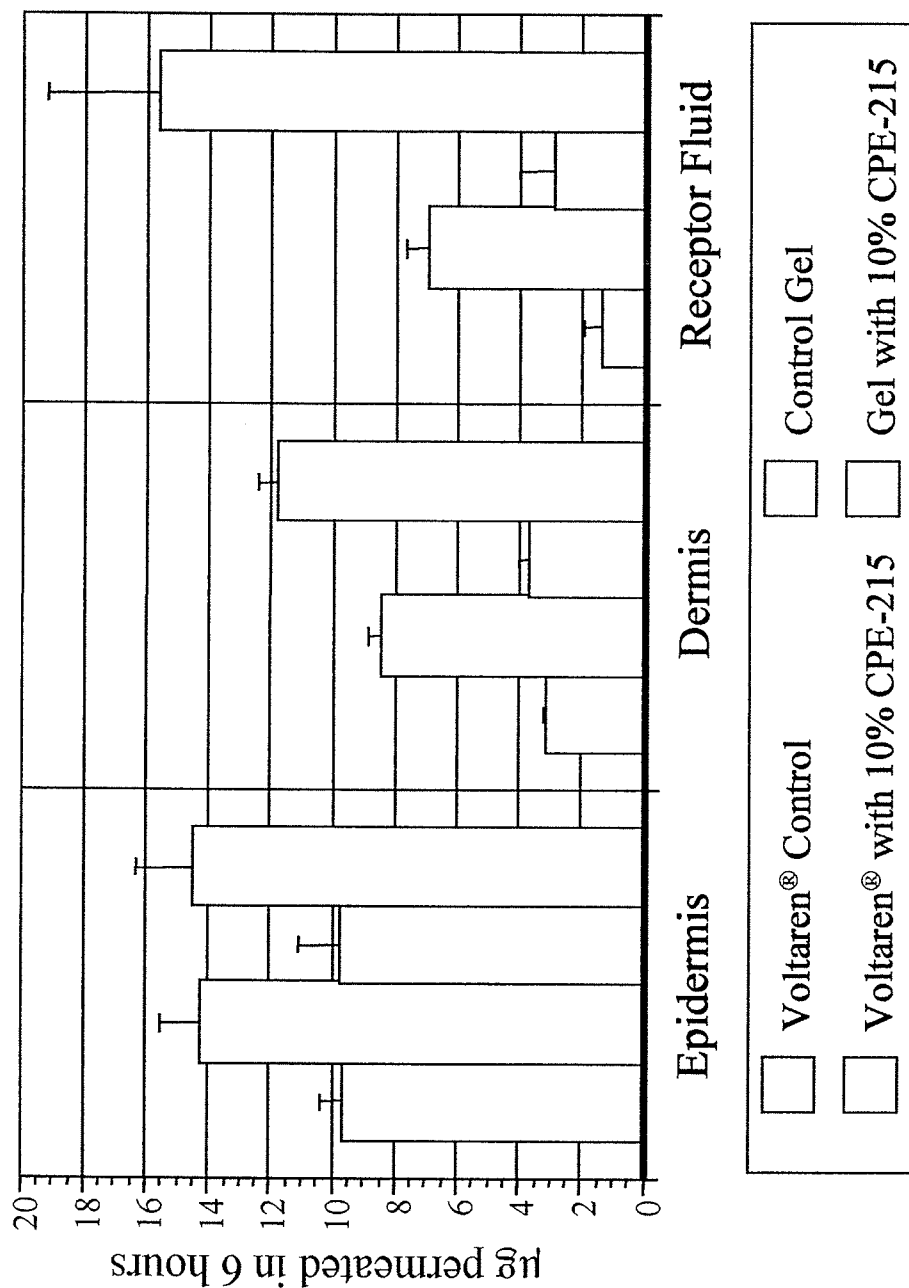
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Diclofenac Permeation Enhancement

1% Gels; 50 mg/0.636 cm² dose-Static cell/Hairless Rat

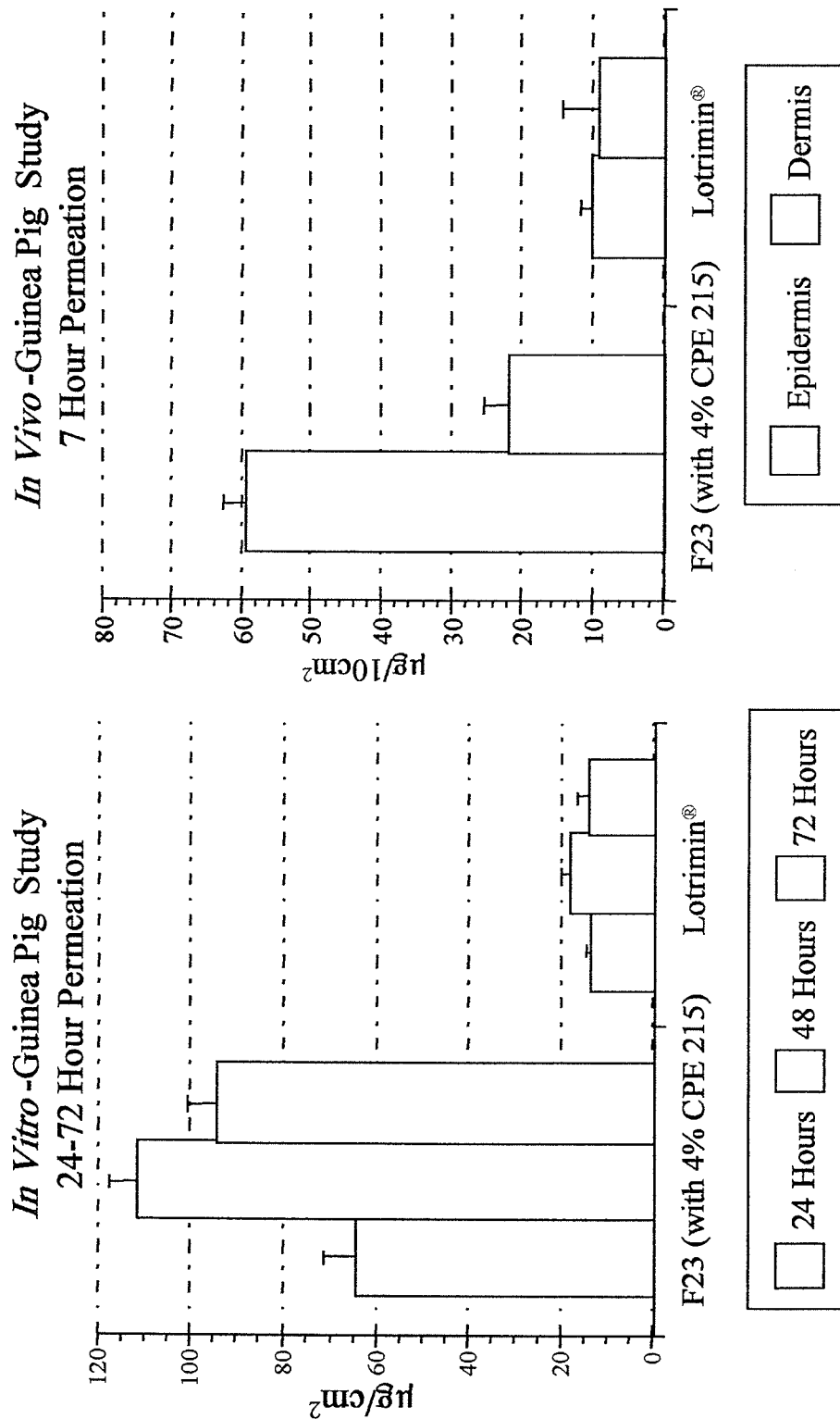


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In Vitro-In Vivo Correlation: Clotrimazole 1% Gels



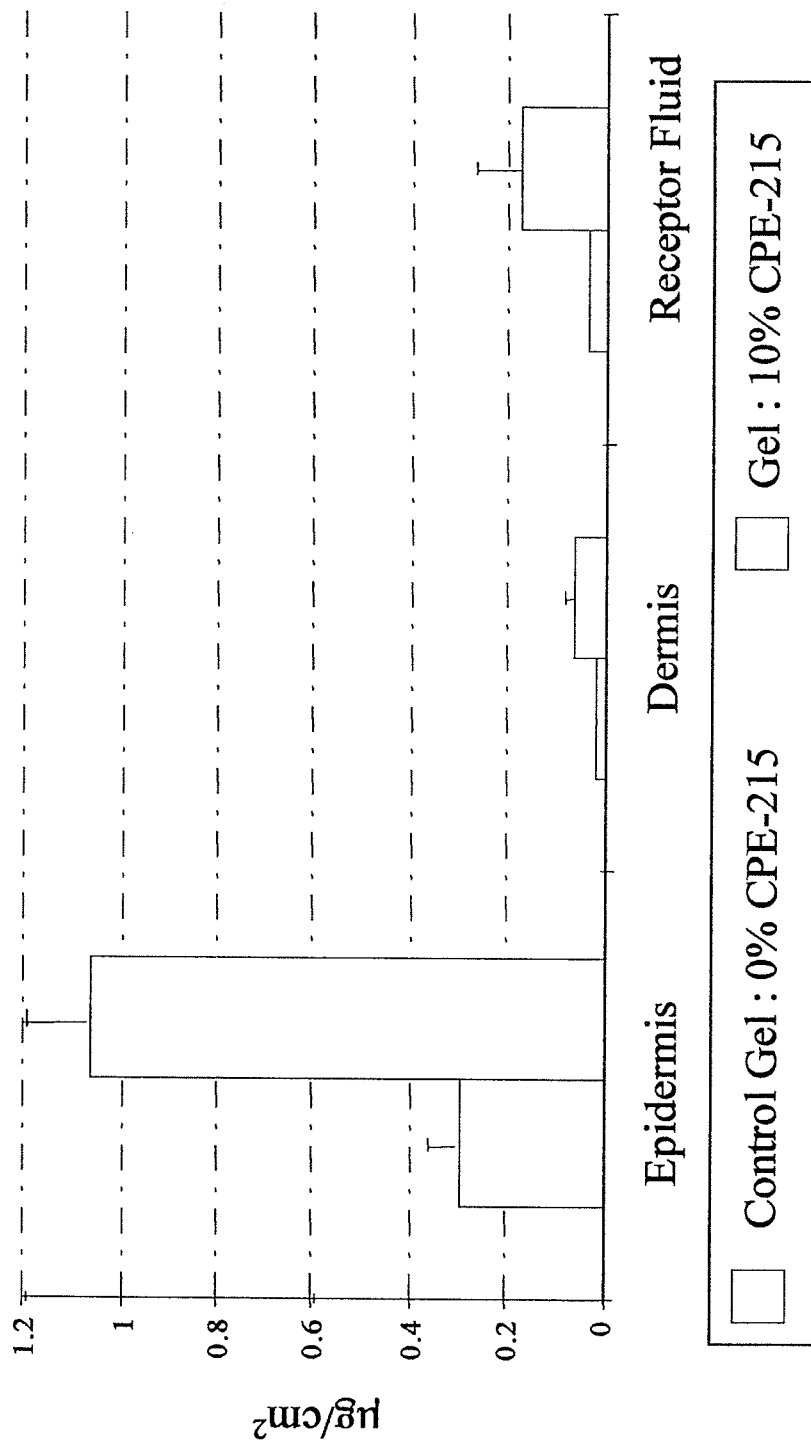
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1% Itraconazole Permeation Enhancement

6 Hour Permeation Study
In Vitro - CD Hairless Rat



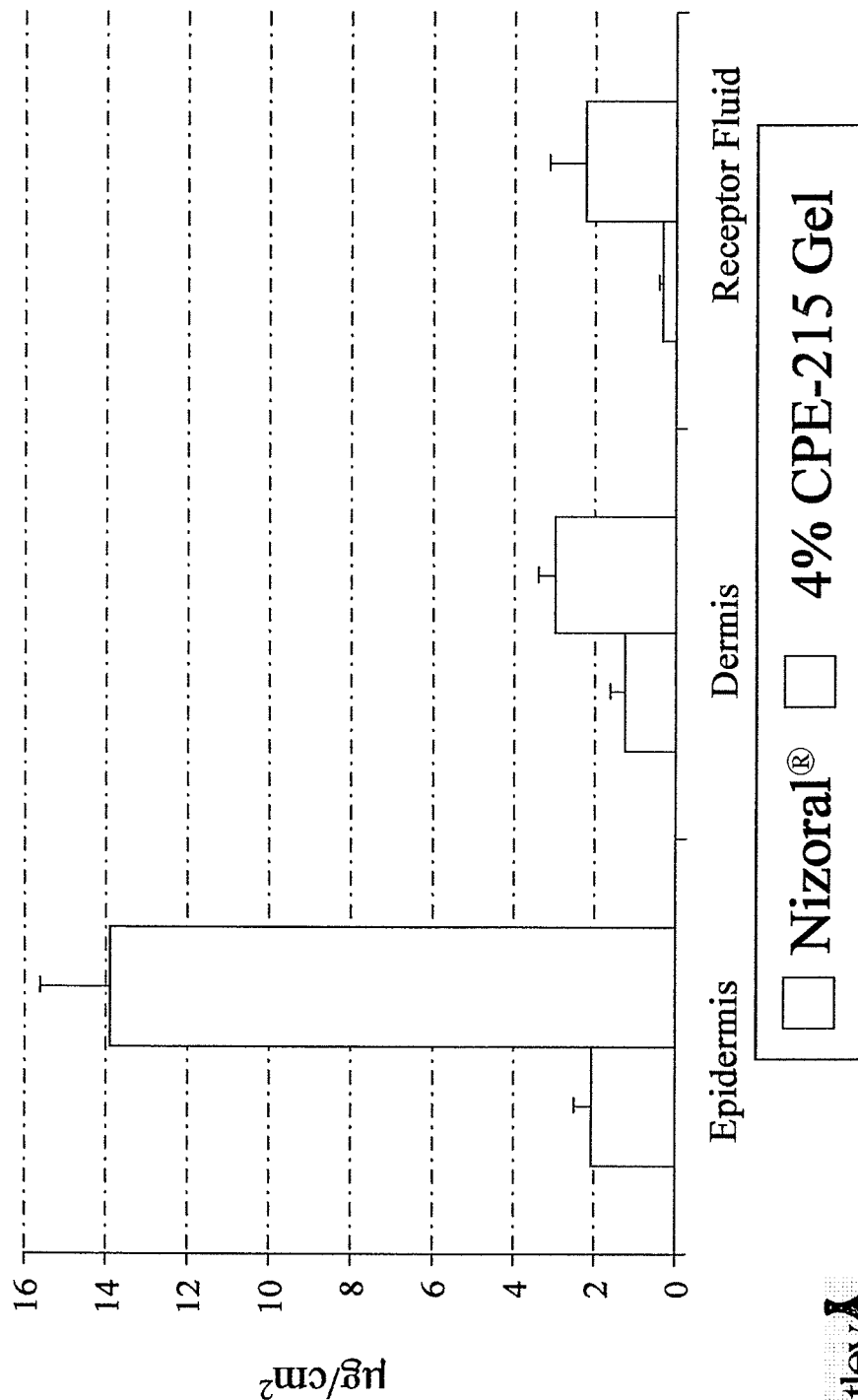
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2% Ketoconazole Permeation

6 Hour Permeation Study
In Vitro - CD Hairless Rat



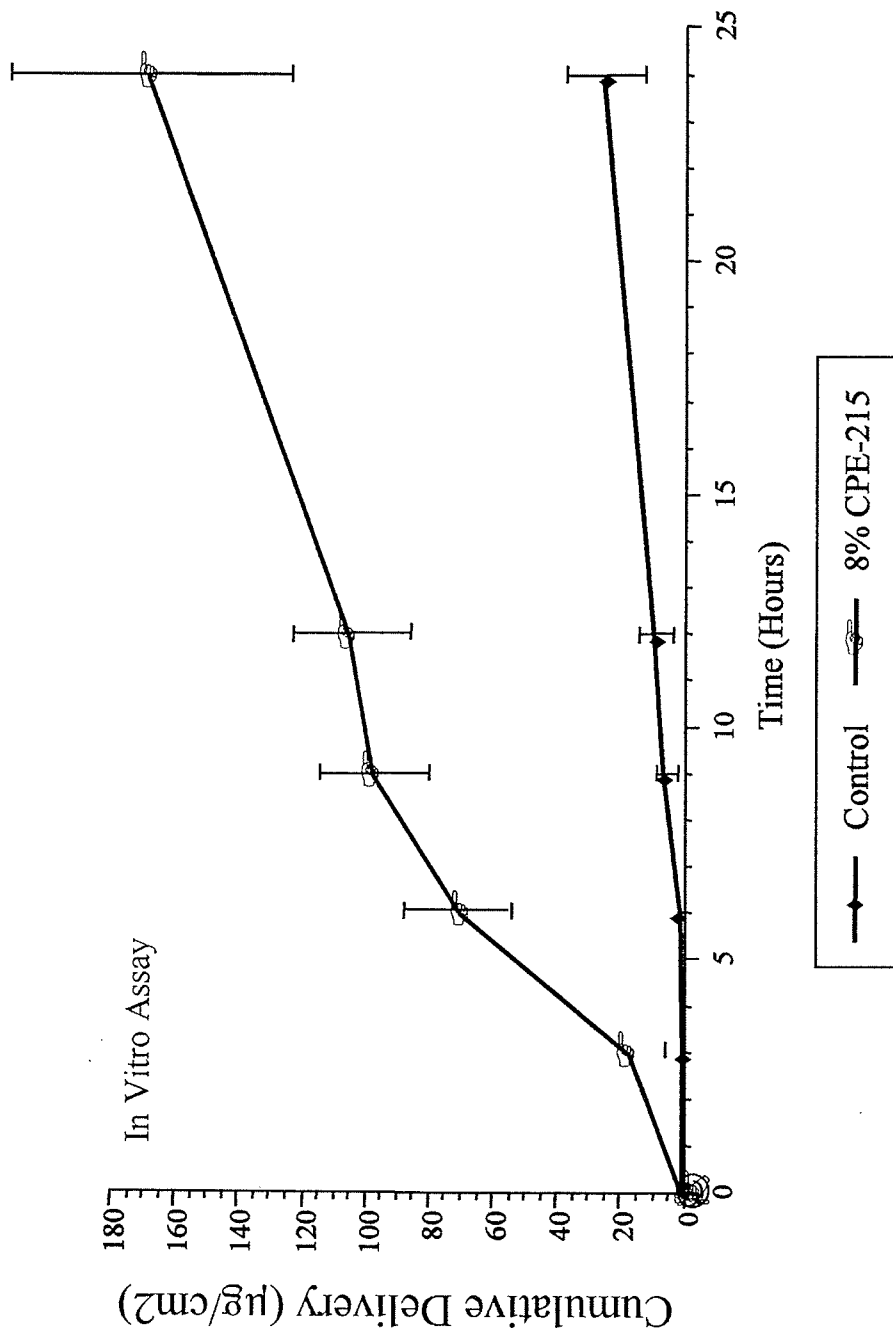
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Testosterone Gel Permeation Enhancement



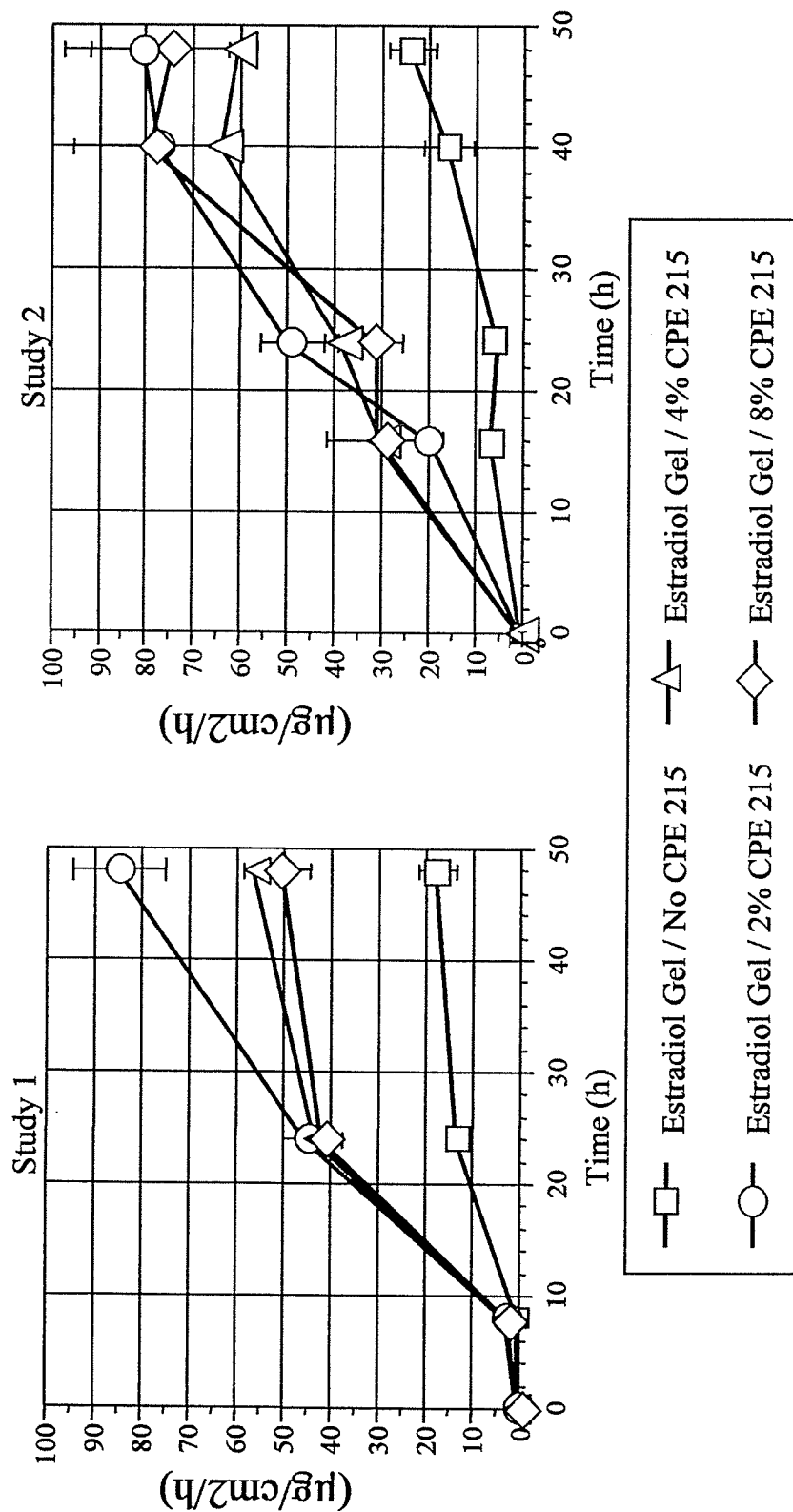
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Estradiol Permeation Enhancement

Two Parallel Studies; 0.3% Estradiol Gels



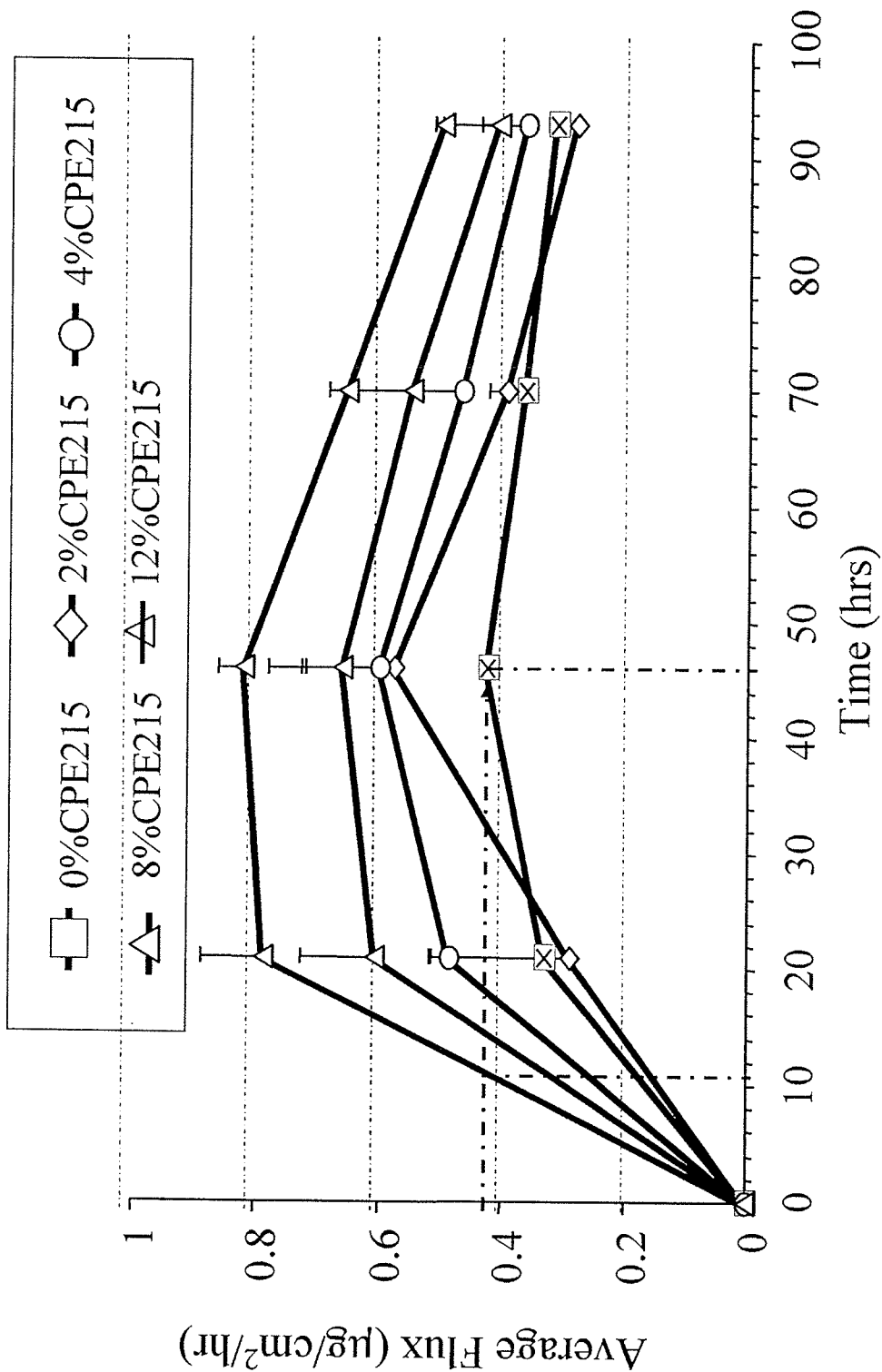
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CPE-215 Enhancement of Estradiol in Patch Formulations



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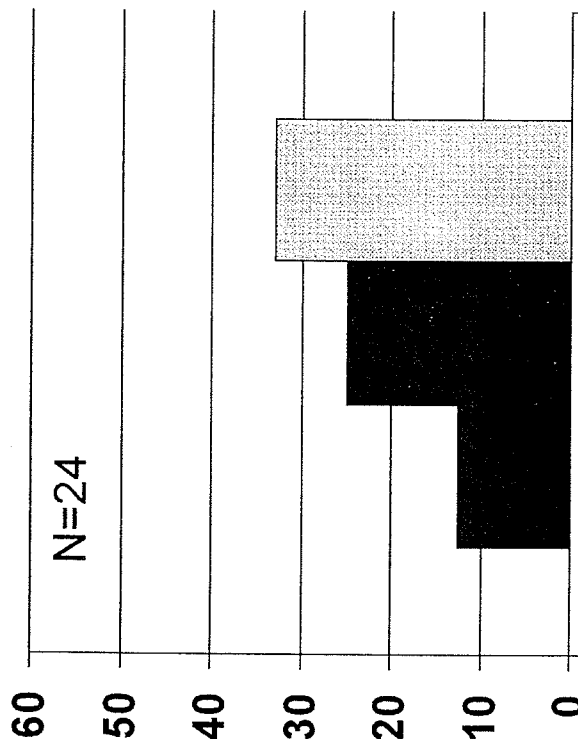
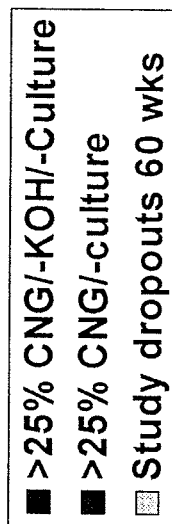
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Clinical studies

Toenail Onychomycosis

4% Clotrimazole with 15% CPE



48 weeks treatment with 12 weeks follow-up

Patients with:

- 25-100% Clear Nail Growth & (-)KOH & (-) Culture at 60 weeks = 12.5% (3/24)
- 25-150% Clear Nail Growth & (-)Culture at 60 weeks = 25% (6/24)

Noncompleters/Drop outs in study by 60 weeks = 33% (8/24)



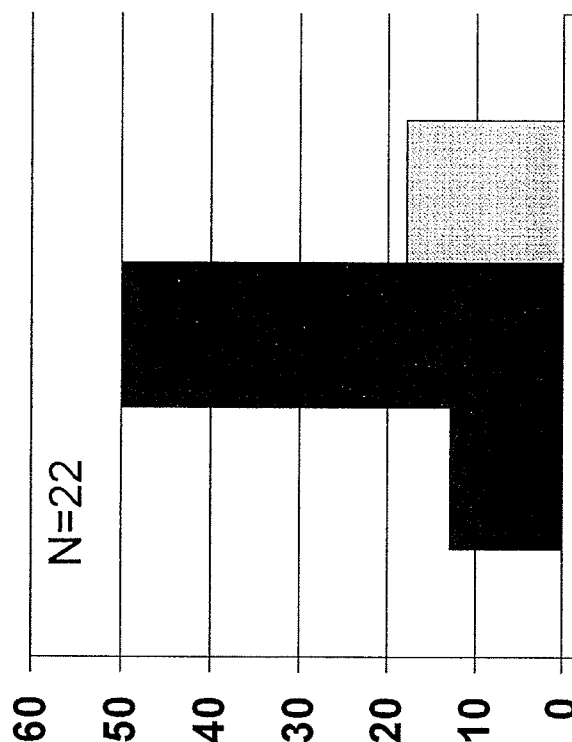
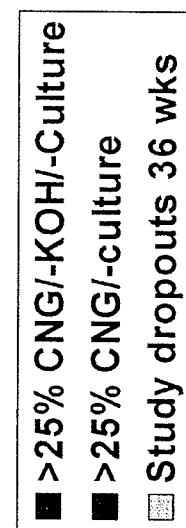
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Fingernail Onychomycosis

4% Clotrimazole with 15% CPE



24 weeks treatment with 12 weeks follow-up

Patients with:

➤ 25-350% Clear Nail Growth & (-)KOH & (-)Culture at 36 weeks = 13% (3/22)

➤ 20-400% Clear Nail Growth & (-)Culture at 36 weeks = 50% (11/22)

Noncompleters/Drop outs in study by 36 weeks = 18% (4/22)



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Testim® (Auxilium Pharma) – Plasma Testosterone

Table 1. Geometric mean (CV%) C_{max} and AUC_{0-24} for testosterone

	C_{max} (ng/dl)	AUC_{0-24} (ng·h/dl)
Testim™	480 (70.3)	5864.5 (77.9)
AndroGel®	368 (60.9)	4499.1 (77.9)

Biopharm. Drug Dispos. 24: 115-120 (2003)

“The ratio of the treatment comparison for both C_{max} and AUC_{0-24} was 1.30, indicating that [serum] values for Testim® were 30% greater than for AndroGel®. The 90% confidence interval for C_{max} ratio was (1.10, 1.55), and for AUC_{0-24} it was (1.08, 1.57). Since neither of these confidence intervals was wholly contained within the bioequivalence limits of 0.80 to 1.25, Testim® and AndroGel® are not bioequivalent.” Copyright # 2003 John Wiley & Sons, Ltd. Biopharm.

Drug Dispos. 24: 115-120 (2003)



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Testim® (Auxilium Pharma) - Plasma DHT

Table 2. Median (range) C_{max} and AUC_{0-24} for dihydrotestosterone^a

	C_{max} (pg/ml)	AUC_{0-24} (pg·h/ml)
Testim™	321 (23-964)	4891.0 (257.5-15259.1)
AndroGel®	313 (16-1038)	4091.7 (225.0-16034.5)

^a Excluding one patient for AUC_{0-24} because there was insufficient sample volume for analysis in Period 2.

“For both C_{max} and AUC_{0-24} , median values for Testim® were greater than for AndroGel® (see Table 2). For C_{max} , the estimated treatment ratio was 1.19, indicating that values for Testim® were greater than for AndroGel®. Similarly for AUC_{0-24} , the estimated treatment ratio was 1.11. The 90% confidence interval for C_{max} ratio was (0.91, 1.36), and (0.95, 1.32) for AUC_{0-24} . As neither of these confidence intervals was wholly contained within the bioequivalence limits of 0.80 to 1.25, Testim® and AndroGel® are not bioequivalent.” Copyright # 2003 John Wiley & Sons, Ltd. Biopharm. Drug Dispos. 24: 115-120 (2003)



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CPE-215 containing products

	Preclinical	Ph I	Ph II	Ph III	Mkt
Onychomycosis	Terbinafine lacquer		Clotrimazole lacquer		
Diabetes		Nasal Insulin			
Hormonal steroids	Estradiol gel Androgenic gel*				Testim® gel*
Severe pain	Nasal narcotic*				
Ophthalmic	Indomethacin Timolol				
Antiinflammatory	Diclofenac gel				
Antifungal	Itraconazole gel Ketoconazole gel				

* In partnership with Auxilium Pharmaceuticals Inc.

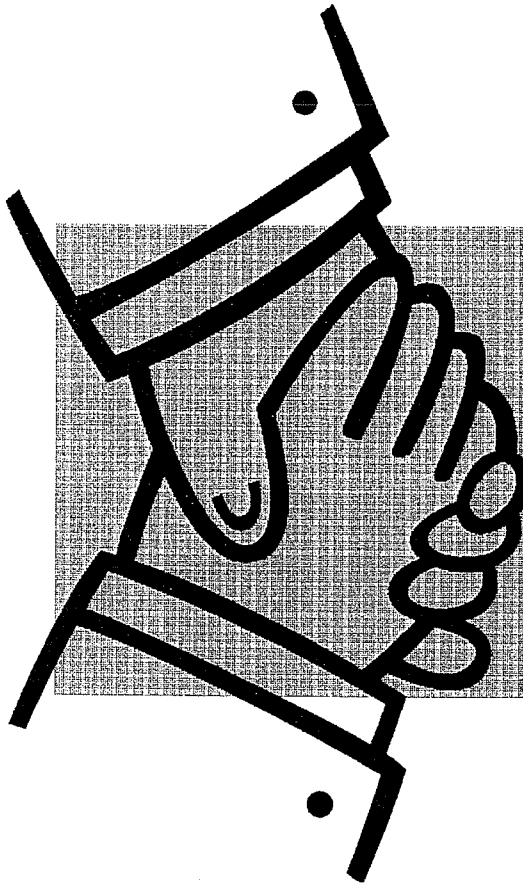


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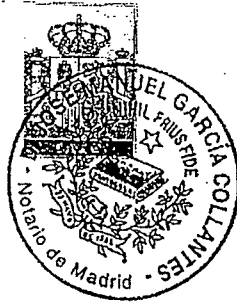
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PAPEL EXCLUSIVO PARA DOCUMENTOS NOTARIALES



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DON JORGE ESPINOSO FERNÁNDEZ, Secretario del
Consejo de Administración de la sociedad
"LABORATORIOS BELMAC, S.A.", SOCIEDAD ANÓNIMA, de
la que es su Presidente don James-Richard Murphy,

CERTIFICA:

Que en el Libro de Actas de la Sociedad aparece
la del siguiente tenor literal:

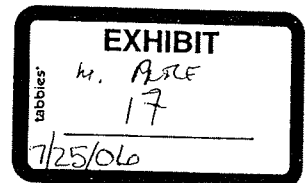
"En San Sebastián de los Reyes, Madrid, a
treinta de diciembre del dos mil tres.

Estando presente en el domicilio social el único

socio de la sociedad, así como todos los miembros
del Consejo de Administración, según resulta de la
lista de asistentes que figura en el libro de
Actas, acuerdan constituirse en Junta General
Universal de Accionistas.

La reunión se celebra bajo la Presidencia de D.
James R. Murphy, actuando D. Jorge Espinoso
Fernández como Secretario, siendo ambos Presidente
y Secretario no Consejero, respectivamente, del
Consejo de Administración.

Jem



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El único socio de la sociedad adoptó los siguientes acuerdos: -----

PRIMERO: En base a la ampliación de capital acordada por compensación de créditos en la Junta General Extraordinaria celebrada el 1 de abril del 2.003, previo informe favorable del órgano de administración que fue presentado a la Junta en aquella fecha, basado en el informe de auditoría de cuentas anuales del ejercicio terminado el 31 de diciembre del 2.002, realizado por el Auditor de Cuentas de la Sociedad, "Deloitte & Touche, S.A., con fecha 24 de febrero del 2.003, cuentas que fueron aprobadas en Junta General Ordinaria de fecha 30 de junio de 2003, y conforme al informe especial para la ampliación de capital por compensación de créditos, de fecha 30 de diciembre del 2.003 realizado por el mismo Auditor, en los cuales se hace constar que los créditos son líquidos, vencidos y exigibles: -----

Ampliar el capital social, por compensación de créditos, en seis millones seiscientos setenta y tres mil trescientos cincuenta y nueve euros setenta y seis céntimos más, mediante la creación y

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puesta en circulación de un millón ciento diez mil trescientas setenta y seis nuevas acciones, de seis euros un céntimo de valor nominal cada una, de la misma serie y con los mismos derechos y obligaciones que las ya existentes, numeradas correlativamente del 250.001 al 1.360.376, ambos inclusive, con la consiguiente modificación del artículo correspondiente de los Estatutos Sociales, cuya redacción final se indicará más adelante. ----

SEGUNDO - La suscripción de las nuevas acciones emitidas, previa renuncia efectuada por la única socia de la sociedad a ejercitar su derecho de preferente adquisición, se realiza por compensación de créditos, por las sociedades: -----

"Pharma España Inc", (domiciliada en Bentley Park, 2, Holland Way, Exeter, NH 03833) que suscribe ciento veintitrés mil cuatrocientas setenta y ocho acciones nominativas, números 250.001 al 373.478, ambos inclusive, por su total importe de setecientos cuarenta y dos mil ciento

gms

⑤

1,502.500
6673.359,76
8 175 859 76

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dos euros setenta y ocho céntimos. -----

Y por "Bentley Pharmaceuticals, Inc",
(domiciliada en Bentley Park, 2, Holland Way,
Exeter, NH 03833), que suscribe novecientas ochenta
y seis mil ochocientas noventa y ocho acciones,
números 373.479 al 1.360.376, ambos inclusive, por
su total importe de cinco millones novecientos
treinta y un mil doscientos cincuenta y seis euros
noventa y ocho céntimos. -----

El importe total de la ampliación de capital ha
quedado ingresado en la Caja Social, reflejando el
correspondiente asiento contable. -----

Asimismo se hace constar que la suscripción de
las nuevas acciones se ha hecho constar en el Libro
Registro de Acciones Nominativas. -----

TERCERO - Como consecuencia de la ampliación de
capital efectuada, en lo sucesivo el artículo 6º de
los Estatutos Sociales tendrá la siguiente
redacción: -----

"ARTICULO 6º.- El capital social es de OCHO
MILLONES CIENTO SETENTA Y CINCO MIL OCHOCIENTOS
CINCUENTA Y NUEVE EUROS SETENTA Y SEIS CÉNTIMOS.
Está dividido y representado por un millón

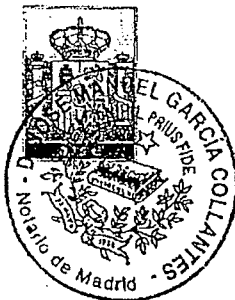
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trescientas sesenta mil trescientas setenta y seis acciones nominativas, de 6'01 euros de valor nominal cada una, totalmente suscritas y desembolsadas, numeradas correlativamente del 1 al 1.360.376, ambos inclusive, cuyos títulos podrán ser unitarios o múltiples y contendrán todos los requisitos legales y la firma de un administrador."

CUARTO - El Órgano de Administración, hace constar que por la compensación de créditos realizada, la deuda con la mercantil "Pharma de España Inc", es de 4'86 euros y la deuda con la mercantil "Bentley Pharmaceuticals Inc." es de 1'10 euros, ambas a 31 de diciembre de 2002. -----

QUINTO - Se faculta expresamente a cualquiera de los miembros del Consejo de Administración para elevar a públicos los precedentes acuerdos, así como para aclarar o subsanar los mismos, en base a la calificación registral, hasta conseguir su inscripción en el Registro Mercantil. -----

Y no habiendo más asuntos que tratar, se levanta

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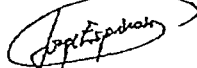
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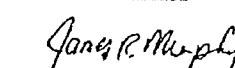
la sesión y de ella la presente acta que es
aprobada y firmada a continuación por todos los
asistentes."

Y PARA QUE CONSTE expido la presente
certificación, en San Sebastián de los Reyes,
Madrid, a treinta de diciembre del dos mil tres.

EL SECRETARIO


Jorge Espinosa

V.B. EL PRESIDENTE


James R. Murphy

15/23

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[Seal] José Manuel García Collantes – Notary of Madrid

JORGE ESPINOSO FERNÁNDEZ, Secretary of the Board of Directors of the "LABORATORIOS BELMAC, S.A." SOCIEDAD ANÓNIMA corporation, whose President is Mr. James Richard Murphy, hereby

CERTIFIES:

That in the Company's Minute Book there appear the following minutes, copied verbatim:

"In San Sebastián de los Reyes, Madrid, on the thirtieth day of December, two thousand three,

The company's sole owner and all the members of its Board of Directors being present at the corporate headquarters, as is evidenced by the list of persons attending which is reflected in the Minute Book, they agreed to convene a Universal Meeting of Shareholders.

The meeting was held under the chairmanship of Mr. James E. Murphy, with Mr. Jorge Espinoso Fernández acting as Secretary. Both the President/Chairman and the Non-Director Secretary, respectively, of the Board of Directors were present.

(handwritten): 1,502,500
6,673,359.76

8,175,859.76

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The company's sole owner adopted the following resolutions:

FIRST: Based on the capital increase agreed upon to offset debts at the Special Meeting of Shareholders held on April 1, 2003, following a favorable report by the company's administrative organ which was submitted to the Board on that date, and based on the report on the audit of the annual accounts for the fiscal year ended December 31, 2002, drawn up by the company's auditor of accounts the "Deloitte & Touche, S.A." firm, dated February 24, 2003, which accounts were approved at the Regular Meeting of Shareholders held on June 30, 2003, and in accordance with the special report for capital increase to offset debts dated December 30, 2003, issued by the same Auditor, in which it is evidenced that the debts are liquid, due and payable.

Increase the capital stock to offset debts, by the sum of six million six hundred seventy three thousand three hundred fifty nine euros and seventy six cents more, through the creation and

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placement in circulation of one million one hundred ten thousand three hundred seventy six new shares with a par value of six euros and one cent each, of the same series and with the same rights and obligations as those now in existence, numbered consecutively from 250,001 to 1,360,376, inclusive, and accordingly to amend the corresponding article of the Corporate Bylaws, whose final wording shall be indicated below:

SECOND. To subscribe for the newly issued shares following the sole owner's waiver of his preemptive right to acquire them, to offset debts owed to the following companies:

"Pharma España Inc." (domiciled in Bentley Park 2, Holland Way, Exeter, NH 03833), which subscribes for one hundred twenty three thousand four hundred seventy eight registered shares numbered from 250,001 to 373,478, inclusive, for the total sum of seven hundred forty two thousand one hundred

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two euros and eight cents.

And "Bentley Pharmaceuticals, Inc." (domiciled in Bentley Park 2, Holland Way, Exeter, NH 03833), which subscribes for nine hundred eighty six thousand eight hundred ninety eight shares numbered from 373,479 to 1,360,376, inclusive, for a total sum of five million nine hundred thirty one thousand two hundred fifty six euros and ninety eight cents.

The total amount of the capital increase has been paid into the company's fund, and is reflected in the accounting records.

A record is likewise made of the fact that the subscription of the new shares has been recorded in the Registered Share Book.

THIRD. As a consequence of the capital increase so performed, Article 6 of the Corporate Bylaws shall henceforth read as follows:

"ARTICLE 6. The capital stock is EIGHT MILLION ONE HUNDRED SEVENTY FIVE THOUSAND EIGHT HUNDRED FIFTY NINE EUROS AND SEVENTY SIX CENTS. It is divided into and represented by one million

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three hundred sixty thousand three hundred seventy six registered shares with a par value of 6.01 euros each, entirely subscribed for and disbursed, consecutively numbered from 1 to 1,360,376, inclusive, whose stock certificates may be unitary or multiple and shall fulfill all the legal requirements and bear the signature of one administrator."

FOURTH: The administrative organ makes a record of the fact that, as a consequence of this offset of debts, the debt to the "Pharma de España Inc." company is 4.86 euros and the debt to the "Bentley Pharmaceuticals Inc." company is 1.10 euros, both as of December 31, 2002.

FIFTH. Any member of the Board of Directors is expressly empowered to convert the foregoing resolutions into public instruments and to clarify or correct them, on the basis of the registration requirements, culminating in their registration in the Mercantile Registry.

And there being no further business to transact, the meeting is adjourned

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and these minutes are drawn up for it, approved, and signed by all the persons present at the meeting.

AND FOR THE RECORD, I issue this certification in San Sebastián de los Reyes, Madrid, on the thirtieth day of December, two thousand three.

THE SECRETARY

[signed] Jorge Espinozo

APPROVED, THE PRESIDENT/CHAIRMAN

[signed] James R. Murphy

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[Seal] José Manuel García Collantes – Notary of Madrid

DELOITTE

SPECIAL REPORT ON CAPITAL INCREASE TO OFFSET DEBTS, PROVIDED FOR IN ARTICLE
156 OF THE RESTATED TEXT OF THE CORPORATIONS ACT

To the sole shareholder of Laboratorios Belmac, S.A. (single-owner firm):

For the intents and purposes provided for in Article 156 of the Restated Text of the Corporations Act, we issue this Special Report on the proposal to increase the capital stock to offset debts in the amount of 6,673,359.76 euros, submitted by the Administrators on December 30, 2003, which is expressed in the accounting document attached hereto. We have verified, in accordance with generally accepted auditing standards, the information prepared under the Administrators' responsibility in the aforementioned document, in regard to the debts to be used to fund the capital increase, at least 25 per cent of which are liquid, due and payable, and the rest of which will mature in no more than five years.

In our opinion, the attached document, drawn up by the Administrators, provides sufficient information on the debts to be offset to increase the capital stock of Laboratorios Belmac, S.A., at least 25 per cent of which are liquid, due and payable, and the rest of which will mature in no more than five years.

This Special Report has been written solely for the intents and purposes provided for in Article 156 of the Restated Text of the Corporations Act, and accordingly, it may not be used for any other purpose.

DELOITTE & TOUCHE, S.A.
Registered in the R.O.A.C. under N° S0665
[signed] Cristina Villalobos
December 30, 2003

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**REPORT DRAWN UP BY THE ADMINISTRATIVE ORGAN OF LABORATORIOS BELMAC,
S.A.U. IN RELATION TO THE CAPITAL INCREASE FOR OFFSET OF DEBTS**

It has been resolved to increase the capital stock to offset debts in the amount of six million six hundred seventy three thousand three hundred fifty nine euros and six cents more (6,673,359.76 €), through the creation and placement in circulation of one million one hundred ten thousand three hundred seventy six new shares with a par value of six euros and one cent each, of the same series and with the same rights and obligations as those now in existence, numbered consecutively from 250,001 to 1,360,376, inclusive, and accordingly to amend the corresponding article of the Corporate Bylaws, whose final wording shall be indicated below:

To subscribe for the newly issued shares following the sole owner's waiver of his preemptive right to acquire them, to offset debts owed to the following companies:

"Pharma España Inc.," which subscribes for one hundred twenty three thousand four hundred seventy eight registered shares numbered from 250,001 to 373,478, inclusive, for the total sum of

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seven hundred forty two thousand one hundred two euros and eight cents (742,102.78 €)..

And "Bentley Pharmaceuticals, Inc.," which subscribes to nine hundred eighty six thousand eight hundred ninety eight shares numbered from 373,479 to 1,360,376, inclusive, for a total sum of five million nine hundred thirty one thousand two hundred fifty six euros and ninety eight cents (5,931,256.98 €).

The total amount of the capital increase has been paid into the company's fund, and is reflected in the accounting records.

As a consequence, Article 6 of the Corporate Bylaws shall henceforth read as follows: "*ARTICLE 6. The capital stock is EIGHT MILLION ONE HUNDRED SEVENTY FIVE THOUSAND EIGHT HUNDRED FIFTY NINE EUROS AND SEVENTY SIX CENTS. It is divided into and represented by one million three hundred sixty thousand three hundred seventy six registered shares with a par value of 6.01 euros each, entirely subscribed for and disbursed, consecutively numbered from 1 to 1,360,376, inclusive, whose stock certificates may be unitary or multiple and shall fulfill all the legal requirements and bear the signature of one administrator.*"

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As a consequence of this offset of debts, the debt in being as of the end of the fiscal year ended December 31, 2002 to the "Pharma de España Inc." company is 4.86 euros and the debt to the "Bentley Pharmaceuticals Inc." company is 1.10 euros.

In San Sebastián de los Reyes, December 30, 2003.

[signed] Adolfo Herrera Málaga

[signed] illegible
Secretary of the company

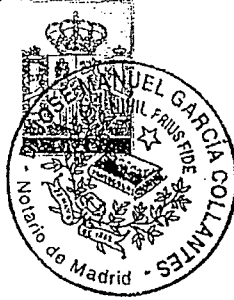
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PAPEL EXCLUSIVO PARA DOCUMENTOS NOTARIALES



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DON JORGE ESPINOSO FERNÁNDEZ, Secretario del Consejo de Administración de la sociedad "LABORATORIOS BELMAC, S.A.", SOCIEDAD ANÓNIMA, de la que es su Presidente don James-Richard Murphy, -

CERTIFICA: -----

Que en el Libro de Actas de la Sociedad aparece la del siguiente tenor literal: -----

"En San Sebastián de los Reyes, Madrid, a treinta de diciembre del dos mil tres. -----

Estando presente en el domicilio social el único socio de la sociedad, así como todos los miembros del Consejo de Administración, según resulta de la lista de asistentes que figura en el libro de Actas, acuerdan constituirse en Junta General Universal de Accionistas. -----

La reunión se celebra bajo la Presidencia de D. James R. Murphy, actuando D. Jorge Espinoso Fernández como Secretario, siendo ambos Presidente y Secretario no Consejero, respectivamente, del Consejo de Administración. -----

Jem

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